REMARKS

Claims 2-14 are pending. By this amendment, claim 10 is amended and claim 14 is added. Claims 2-9 were previously withdrawn. No new matter is introduced. Support for the amendments may be found at least at page 3, lines 14-24, page 5, line20-page 6, line 12, and page 6, lines 18-25 of the specification, and Figure 4. Reconsideration and allowance of all pending claims is respectfully requested in view of the preceding amendments and following remarks.

Rejection under 35 U.S.C. § 102

(a) Luther

Claims 10, 11 and 13 were rejected under 35 U.S.C.§ 102(b) as being anticipated by Luther (U.S. Patent No. 4,790,817). Applicants respectfully traverse this rejection for at least the following reasons.

Luther discloses an assembly of a stylet and catheter, and a needle and catheter. More particularly, as described in column 1, lines 15-20, Luther relates to a stylet providing an axially aligned puncture tip, the stylet being inserted through a catheter to form an assembly which can effectively pierce a vein. Upon withdrawal of the stylet, the catheter remains in place in the vein. As further disclosed in Luther, in operation, the stylet and catheter are inserted into a vein, artery, organ, or the like. Because the catheter remains in place in the vein when the stylet is withdrawn, the proximal end of the catheter must be dislodged from the position against the proximal shoulder of the stylet when the stylet tip is still located in the vein. When the stylet is inserted into the vein, contact of the catheter with blood will cause the catheter tip to expand out of contact from the shoulder of the stylet. When the stylet is retracted, the catheter will remain in place in the user's vein. Column 5, lines 5-17.

Accordingly, Luther does not disclose or teach that a clearance is configured between the inner wall of the cannula and the outer wall of the needle such that in use, a fluid substance is communicated in the clearance, thereby delivering the fluid. To the contrary, in Luther's operation, the stylet is withdrawn, and the fluid substance is communicated within separate feed

bores of the catheter (Figs. 11-16, column 3, lines 19-22; column 5, lines 18-39), not within a clearance between the inner wall of the catheter and the outer wall of the stylet. In reply to this previously asserted argument, the Examiner responded:

> Luther discloses an injection needle and cannula wherein the needle and cannula have different cross-sections resulting in a clearance between the needle and cannula allowing fluid communication within this clearance, resulting in priming...Luther discloses that the clearance allows flashback...Applicant argued...that Luther does not disclose a clearance allowing fluid communication. The examiner disagrees and refers Applicant to...where Luther discusses flashback, and therefore fluid communication. OA dated 3/10/05, p. 3 (emphasis added).

Applicants respectfully assert that the flashback groove of Luther does not disclose the claimed clearance. Specifically, the cannula/needle combination of the present invention is for "administering a fluid substance," and as recited in amended claim 10, "the fluid substance [is] communicated in the clearance, thereby delivering the fluid." In other words, the claims recite a clearance for administering or delivering fluids. In contrast, the flashback groove of Luther does not communicate administered or delivered fluids, but rather it allows blood flashback. Moreover, groove 26 of Luther is configured to allow blood flashback in the opposite direction from that which a fluid substance is delivered. Further, groove 26 is arranged to allow blood flashback during insertion of the stylet, not during administration or delivery of the fluid. Column 4, lines 20-23 ("Consequently, when blood flashes back along the groove after insertion of the stylet into a vein or artery, it will be contained within the groove by the catheter."). Thus, groove 26 of Luther is also not described as extending "substantially along the length of the needle" as recited in claim 14, because groove 26 is not intended for delivering fluids. Nowhere does Luther describe groove 26 being configured or arranged to administer or deliver a fluid substance.

Additionally, the flashback groove of Luther does not communicate a fluid substance as claimed, but rather the groove merely allows some flashback "near the puncture tip rather than at the distal end, or hub of the assembly"; i.e., the goal of the Luther assembly is to make observable undesirable blood flashback near the puncture tip before the blood has the opportunity to be communicated along the assembly to its distal end. Column 1, lines 39-47

("Another problem with prior art needles and cannula is that flashback of blood into the needle is not observed until the blood reaches the distal end or hub portion of the needle. It would be preferable to provide an assembly including a catheter and vein piercing device such that flashback is observed almost immediately, i.e., near the puncture tip rather than at the distal end, or hub of the assembly."); *see also*, column 4, lines 23-26 ("Also, since the catheter is transparent or partially transparent, this flashback will be observable immediately, and will enable the user to determine that the patient's (or user's) vein has been penetrated.").

For at least these reasons, Applicants respectfully submit that claims 10-14 are patentably distinguishable over Luther.

(b) Biscoping

Claims 10-13 were rejected under 35 U.S.C. § 102(b) as being anticipated by Biscoping et al. (U.S. Patent No. 5,135,525). Applicants respectfully traverse this rejection for at least the following reasons.

Biscoping fails to disclose a cannula/needle combination for administering a fluid substance with a clearance between the inner wall of the cannula and the outer wall of the needle such that "the fluid substance [is] communicated in the clearance, thereby delivering the fluid" as claimed. Rather, Biscoping describes a catheter set including an epidural cannula with first and second trocars for continuous spinal anaesthesia. Although Biscoping describes an extending channel 21 through second trocar 17, as was the case with the Luther reference, this groove is not configured to communicate "the fluid substance...thereby delivering the fluid" as claimed, but rather the groove merely drains liquor from the dura when the catheter punctures the dura. *See*, column 3, lines 28-33 ("The second trocar 17 has a through-going longitudinally extending channel 21 which, in the preferred embodiment, is formed as an open groove or notch with an aperture angle of about 80 to 90°. Liquor may drain from this notch, thereby indicating a successful puncturing of the dura."). As with Luther, the configuration of this groove does not allow for delivery of a fluid substance but rather it drains a substance in a direction opposite to delivery. Additionally, extending channel 21 of Biscoping is therefore not described as extending "substantially along the length of the needle" as recited in claim 14, because groove 26

is not intended for delivering fluids. Nowhere does Biscoping describe extending channel 21 being arranged to deliver a fluid.

For at least these reasons, Applicants respectfully submit that claims 10-14 are patentably distinguishable over Biscoping.

(c) Bryant

Claims 10-13 were rejected under 35 U.S.C. § 102(b) as being anticipated by Bryant (U.S. Patent No. 5,201,712). Applicants respectfully traverse this rejection for at least the following reasons.

Independent claim 10 as amended recites "a needle comprising a substantially sharpened piercing end." Bryant fails to disclose a piercing end as claimed. Bryant describes a catheter assembly with a reciprocable obturator for maintaining the patency of the catheter assembly during periods between infusions. Specifically, the catheter of Bryant includes tubular portion 18 defining a lumen and an elongated obturator rod 34 "telescopically disposed within the lumen of the tubular portion of the catheter tubular portion 18." Col. 3, lines 30-32, 44-48; Figs. 1, 2. Additionally, the tip of obturator rod 34 forms a bulbous, circular shape for obturating the opening in tubular portion 18:

> To provide the desired valve-like cooperation between the obturator rod 34 and the tubular portion 18 of the catheter, the obturator rod includes a free end portion having a circular configuration complemental to the circular, cross-sectional configuration of the lumen defined by tubular portion 18. The free end portion of the obturator rod 34 is sized relative to the lumen to provide a sliding seal between the rod and the inside diameter of the tubular portion of the catheter. (Col. 3, lines 55-63; Fig. 4).

Thus, the "free end portion" of the catheter of Bryant is clearly not a "a substantially sharpened piercing end" as claimed. *See* Fig. 4. Functionally, the latter is suitable for, *inter alia*, insertion into tissue whereas the former is not.

Further, newly added claim 14 recites "the clearance extends substantially along the length of the needle." The grooves 38 defined in the obturator rod 34 of Bryant clearly do not

extend along the length of the rod as in claim 14. Rather, the "free end portion" of the obturator rod has a "circular configuration," through which the grooves do not extend. Col. 3, lines 55-60; Fig. 4. For this additional reason, Bryant fails to teach each and every limitation of claim 14.

For at least this reason, Applicants respectfully submit that claims 10-14 are patentably distinguishable over Bryant.

Conclusion

No fees have been generated by this paper, however, a petition to extend the time to respond and a Request for Continued Examination ("RCE") are being submitted herewith, along with the appropriate fees. The Commissioner is hereby authorized to charge any deficiencies and credit any overpayments associated with the RCE, petition or this paper to Deposit Account No. 04-1420.

This application now stands in allowable form and reconsideration and allowance is respectfully requested.

Respectfully submitted,

DORSEY & WHITNEY LLP
Customer Number 25763

Date: June 30, 2005

By: David E Bruhn
David E. Bruhn, Reg. No. 36,762
(612) 340-6317